

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE MEDTRONIC, INC., IMPLANTABLE DEFIBRILLATORS PRODUCTS LIABILITY LITIGATION)))))	MDL No. 05-1726 (JMR/AJB) MASTER CONSOLIDATED COMPLAINT FOR THIRD PARTY PAYOR CASES
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I. INTRODUCTION

1. This Master Consolidated Complaint for Third Party Payor Cases is filed in accordance with the January 20, 2006 Order of this Court, ¶ 17.A.2.

2. In these actions, third party payors such as health and welfare funds, self-insured employers, and non-profit and for-profit health insurers, all of whom bear the ultimate economic risk of health care payments (“third party payors”), bring claims against Medtronic, Inc., for its sale and distribution of defective implantable cardiac defibrillators (“ICD”) and cardiac resynchronization therapy devices (“CRT-D”), and for its otherwise wrongful marketing, promotion, advertising and sale of these devices. By reason of the wrongful conduct of Medtronic, a massive, national recall of approximately 87,000 heart devices has been underway in the United States. The overwhelming economic impact of Medtronic’s conduct and the recall has fallen, wrongfully, on the shoulders of public and private payors of health insurance.

3. These actions seek several forms of relief. First, the actions seek class certification pursuant to Fed. R. Civ. P. 23(b)(2) and 23(b)(3), as well as interim appointments pending those class certifications under Fed. R. Civ. P. 23(g). Second, the actions seek non-monetary relief including disclosure (under appropriate protections for privacy) of the registrant list(s) maintained by Medtronic to enable appropriate effectuation of the recall and the proper allocation of the economic burden of that recall. Third, the actions seek monetary relief

including payment for the wrongful economic burden placed on third party payors for the costs of replacement and/or corrective surgeries. Given the magnitude of the approximately 87,000 recalled devices, the economic costs associated with these expenses will exceed many hundreds of millions of dollars.

4. At all times relevant to this class action, Medtronic knew or should have known that the devices were not safe for the patients who received them because of the failure/short-circuiting of the batteries and/or high voltage capacitors and the resultant effect on the units, rendering the devices unsafe and unreliable. The devices were defective, unreasonably dangerous and unfit for their intended uses. Medtronic placed tens of thousands of patients unnecessarily at risk of serious injury and/or death and caused the Plaintiffs and members of the Class (as defined hereafter) to incur substantially greater costs than they should and otherwise would have paid for medical treatment. These costs will continue to mount and Class members will continue to pay for the consequences of Defendant's actions for years to come.

II. PARTIES

A. Plaintiffs

5. This Master Consolidated Complaint for Third Party Payor Cases has been filed in accordance with the January 20, 2006 Order of this Court. Accordingly, technically there are no "parties-plaintiff" to this document. However, the following three named plaintiffs are set forth in this document because those plaintiffs have, on this date, filed notices adopting this third party payor master complaint as their own.

6. Plaintiff United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund (hereinafter sometimes referred to as "UFCW") is an employee welfare benefit plan and employee benefit plan maintained pursuant to § 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 186(c)(5), and as defined by §§ 1002(1) and

(3) of the Employee Retirement Income Security Act (“ERISA”), 29 U.S.C. § 1001, et. seq. UFCW provides health benefits to approximately 25,000 eligible participants and beneficiaries. UFCW maintains its principal office from which it pays medical benefits in Cook County, Illinois. During the Class Period, UFCW has been billed and paid charges for the Medtronic products at issue in this litigation.

7. Plaintiff The Kinetic Company, Inc. (hereinafter sometimes referred to as “Kinetic”), a Wisconsin corporation, manufactures industrial knives. Kinetic has been a party to a contract, issuer of a policy or sponsor of a plan, which contract, policy or plan provides medical coverage to natural persons. During the class period, Kinetic has been billed for and paid charges for Medtronic products at issue in this litigation as described herein.

8. Plaintiff The Guardian Life Insurance Company of America (hereinafter sometimes referred to as “Guardian”) is a mutual life insurance company organized and existing under the laws of the state of New York with its headquarters located at 7 Hanover Square, New York, New York 10003. Founded in 1860, The Guardian Life Insurance Company of America is the fourth largest mutual life insurance company in the United States. As of December 31, 2004, Guardian and its subsidiaries had \$39.5 billion in assets. With more than 5,000 employees and 2,900 financial representatives, as well as over 80 agencies nationwide, Guardian and its subsidiaries protect individuals, businesses and their employees with life, disability, health and dental insurance products, and offer 401(k), financial products and trust services. During the class period, Guardian’s health insurance policies covered claims for medically necessary devices including ICDs and CRT-Ds and Guardian has paid or reimbursed for certain of the Medtronic products at issue in this litigation.

9. The named plaintiffs above, and each plaintiff hereinafter adopting this complaint, have sustained economic loss in the form of full or partial payment for costs of the recalled cardiac devices and related medical expenses including the original defective device, implantation surgery, replacement device, replacement surgery, medical monitoring and additional related medical expenses by virtue of Defendant's wrongful conduct.

B. Defendant

10. Defendant Medtronic, Inc. is a publicly traded corporation, duly formed and existing under and by virtue of the laws of the state of Minnesota, with its principal place of business located at 710 Medtronic Parkway, Minneapolis, Minnesota. Medtronic describes itself as a "global leader in medical technology" and as of April 29, 2005 posted \$10.055 billion in revenue. It employs approximately 32,000 employees worldwide.

11. Medtronic researches, develops, tests, manufactures, markets, promotes, advertises and sells implantable cardiac defibrillators ("ICDs") and cardiac resynchronization therapy devices ("CRT-Ds"), including the capacitors and batteries required for their operation. Medtronic's Cardiac Rhythm Management (CRM) business "develops products that restore and regulate a patient's heart rhythm, as well as improve the heart's pumping function." Through the CRM division, Medtronic developed, manufactured, tested, marketed and sold the Recalled Cardiac Devices, as well as the batteries required to power them. Medtronic's CRM business markets "implantable pacemakers, defibrillators, cardiac ablation catheters, monitoring and diagnostic devices and cardiac resynchronization devices, including the first implantable device for the treatment of heart failure."

III. JURISDICTION AND VENUE

12. This Court has diversity subject-matter jurisdiction over this class action pursuant to the Class Action Fairness Act of 2005, which, *inter alia*, amends 28 U.S.C. § 1332 to add a

new subsection (d) conferring federal jurisdiction over class actions where, as here, “any member of a class of plaintiffs is a citizen of a State different from any defendant” and the aggregated amount in controversy exceeds five million dollars (\$5,000,000). *See* 28 U.S.C. §§ 1332(d)(2) and (6). This Court has personal jurisdiction over the parties because each plaintiff submits to the jurisdiction of the Court and Defendant systematically and continually conducts business throughout the state of Minnesota, including marketing, advertising and sales of the Recalled Cardiac Devices.

13. Venue in this jurisdiction is proper pursuant to 28 USC § 1391(a) as: (i) Medtronic maintains offices in Minnesota and its CRM Operations is headquartered in Minnesota; (ii) Medtronic sells and markets the Recalled Cardiac Devices within Minnesota and on a national basis; and (iii) Medtronic’s CRM facilities operate in Minneapolis, Minnesota, its principal place of business for manufacturing, research and development, administration, sales and marketing, warehousing, packaging, shipping and safety reporting on/of medical devices (including the Recalled Cardiac Devices). Upon information and belief, the actions and conduct giving rise to the claims at issue took place and emanated from these facilities.

IV. FACTUAL ALLEGATIONS

A. Use of Heart Devices

14. Cardiovascular disease is the leading cause of death for both men and women in the United States and claims more lives each year than the next five leading causes of death combined. Approximately five million people in the United States alone suffer from heart disease. Implantable cardiac defibrillators (“ICDs”) and cardiac resynchronization therapy devices (“CRT-Ds”) focus on the treatment of cardiovascular and peripheral disease, cardiac arrhythmias, heart failure and slow heartbeats.

15. ICDs have been one of the most popular and fastest growing types of medical devices. Over 200,000 patients received an ICD in 2005.

16. A person with cardiovascular disease requires an ICD as a monitor and response mechanism when the heart develops a chaotic or irregular rhythm. ICDs monitor, regulate and stabilize the heart in the event of an increase or decrease in heart rhythm or sudden heart failure. If a cardiac disturbance occurs, the function of the ICD is to deliver an electric shock to the heart to restore the heart to sinus rhythm. ICDs are powered by a battery sealed within the device. The power source is implanted in a pouch formed in the chest wall and connected directly to the heart muscle via an insulated lead wire. Electrodes that sense the heart's rhythm are placed in the heart. Electric currents are sent from the ICD through said insulated leads to the heart, which is shocked back into a steady rhythm.

17. Patients who suffer from abnormally fast heart rhythms (tachycardia), rapid, ineffective contraction of the ventricles of the heart (ventricular fibrillation) or significant thickening of the heart muscle are also treated with ICDs to regulate heart rhythms. Without the aid of an ICD, these conditions and arrhythmias can lead to cardiac arrest or sudden death.

18. Similarly, CRT-Ds are designed to provide mild electrical impulses to the two lower chambers of the heart to rectify and ameliorate heart failure symptoms and allow the heart to beat in a normal sequence.

19. During a heart failure episode, a patient's survival depends upon the success of the device detecting the problem and shocking the heart back to a regular rhythm. Without a prompt response, a patient faces great peril – and potential loss of life – and may require external resuscitation from medically trained personnel. If functioning properly, ICDs can save lives. If

a device fails to engage during an arrhythmic episode, a patient in cardiac arrest has only minutes before death or permanent injuries occur.

B. Medtronic ICDs and CRT-Ds

20. Medtronic researches, develops, manufactures, promotes, advertises and markets health care products, including ICDs and CRT-Ds. In the most recent reporting period, Medtronic stated that approximately two million of its cardiac devices have been implanted in patients world-wide.

21. Medtronic's CRM business "develops products that restore and regulate a patient's heart rhythm, as well as improve the heart's pumping function." Through the CRM division, Medtronic developed, manufactured, tested, marketed and sold the Recalled Cardiac Devices, as well as the batteries required to power them. Medtronic Inc.'s facilities in Minnesota are the primary site of CRM operations.

22. Medtronic's CRM business – its largest business segment – includes all of its ICD and CRT-D devices, which accounted for nearly fifty percent of the company's worldwide sales. ICDs have been Medtronic's fastest growing product for the past three years: between 2002 and 2005, Medtronic's revenues from sales of the devices rose by nearly 63 percent from \$2.944 billion to \$4.615 billion.

23. In its public disclosures, Medtronic has represented to physicians, patients, Class members and others that its ICDs and CRT-Ds are essential for saving lives. For example, Medtronic asserts that "[p]hysicians rely on our CRM products to correct these irregularities and restore the heart to its normal rhythm. Our CRM products are designed to treat a broad range of heart conditions."

C. Medtronic's Devices are Recalled

24. On or about April 4, 2004, the United States Food and Drug Administration ("FDA") announced a Class I Recall of two models of ICDs: Micro Jewell II (Model 7223Cx) and GEM DR (Model 7271) (collectively the "Class I Recalled ICDs"). Class I Recalls are instituted only when there exists a reasonable probability that use of the product will cause serious injury or death. The Micro Jewell II was manufactured between November 1996 and December 1997. The GEM DR was manufactured between May 1997 and August 1998.

25. On April 16, 2004, Medtronic issued a press release announcing the recall of the Class I Recalled ICDs. In the press release, Medtronic noted that it had become aware "of one serious injury and four deaths that may be related to the failure of the capacitor in a small subset of Micro Jewell II devices."

26. The Class I Recalled ICDs were found to have defective high voltage capacitors resulting in holdups in recharging the device's battery. Such holdups could cause delays in the device's delivery of needed shock therapy or cause the device to fail to deliver that therapy when a cardiac arrhythmia occurs. Delays in delivery or failure to deliver shock therapy during a cardiac arrhythmia can cause patient injury and/or death.

27. On or about February 11, 2005, Medtronic initiated a worldwide advisory/recall regarding four additional models of ICDs manufactured between April 2001 and December 2003: Marquis VR (Model 7230); Marquis DR (Model 7274); Maximo VR (Model 7232); and Maximo DR (Model 7278) (collectively the "Recalled ICDs").

28. On or about February 11, 2005 Medtronic also initiated a worldwide advisory/recall regarding four models of CRT-Ds manufactured between April 2001 and December 2003: InSync Marquis (Model 7277); InSync II Marquis (Model 7289); InSync III Marquis (Model 7279); and Model 7285 (collectively the "Recalled CRT-Ds"). (The Class I

Recalled ICD's, Recalled ICDs and the Recalled CRT-Ds are collectively referred to as the "Recalled Cardiac Devices.")

29. Concurrently, the FDA published Medtronic, Inc.'s notice regarding the Recalled ICDs and Recalled CRT-Ds and stated Medtronic was "advising physicians about a potential battery shorting mechanism" in the Marquis VR/DR and Maximo VR/DR ICDs and the InSync I/II/III Marquis and InSync III Protect CRT-D devices.

30. The Recalled ICDs and Recalled CRT-Ds contained a potential battery shorting mechanism. When an ICD short-circuits, it causes the device to fail or stop working properly, placing the patient at significant risk of serious injury or loss of life when a cardiac disturbance occurs. Without a medical examination during an actual failure, a patient would not know of the device failure until moments before going into cardiac arrest.

31. In a letter to physicians, Medtronic related that in its testing of returned devices, batteries in the Recalled ICDs and Recalled CRT-Ds were found to have "rapid battery depletion due to this shorting action. If shorting occurs, battery depletion can take place within a few hours to a few days, after which there is loss of device function." Medtronic noted that this shorting mechanism would potentially increase to a higher rate of incidence over the second half of the device life.

32. Due to the nature of the defect, it would not have been possible for any Class member to discover the existence of the capacitor or battery short-circuit problems in the Recalled Cardiac Devices until Medtronic and/or the FDA identified the defects and notified the public: February 10, 2005 in the case of the Recalled ICDs and Recalled CRT-Ds (the date of Medtronic's first communications to physicians), and April 4, 2004 in the case of the Class I

Recalled ICDs. Medtronic's failure to properly disclose and/or concealment of a known defect from Plaintiff and the Class members constitute fraudulent concealment.

33. Altogether, Medtronic's recalls and advisories of the above specified models affect approximately 87,000 patients and devices.

D. Medtronic Failed to Comply with FDA Requirements and Misrepresented the Safety of the Recalled Cardiac Devices

34. Although Medtronic did not advise the FDA, patients or physicians of the battery failure problems, the company was aware of these issues as early as January 2003. Instead, in August 2003, Medtronic requested approval from the FDA for a change in the batteries without notifying the FDA of the reason for the change. The FDA approved this change in October 2003 and ICDs containing the new battery began selling in December 2003.

35. Despite making the battery change, Medtronic continued to market, sell and distribute the previously manufactured devices - knowing they were defective and prone to failure – until the stock was depleted. Patients continued to receive the defective devices for all of 2003, all of 2004 and at least until February 2005.

36. At all times relevant to this action, Medtronic misrepresented the safety of the Recalled Cardiac Devices, as well as their batteries, and negligently manufactured, marketed, advertised, promoted, and sold them as safe devices to be used for the prophylactic treatment of patients who have had spontaneous and/or inducible life-threatening ventricular arrhythmias and patients who are at high risk for developing such arrhythmias.

37. At all times relevant to this action, Defendant knew, and/or had reason to know, that the Recalled Cardiac Devices were not safe for the patients for whom they were prescribed and implanted because the devices short circuit and malfunction and therefore fail to operate in a

safe and continuous manner, causing serious medical problems and, in certain patients, catastrophic injuries and deaths.

38. As a result of their defective design and manufacture, the Recalled Cardiac Devices can cause serious physical trauma and/or death. Defendant knew, and/or had reason to know, of this tendency and the resulting risk of injury and death and, by failing to disclose the information, prevented Plaintiffs, the Class, and physicians from making informed decisions about the implantation of the ICDs and CRT-Ds at issue herein.

39. Defendant knew, and/or had reason to know, that its deceptive behavior and failure to disclose the malfunctions of the Recalled Cardiac Devices would cause Plaintiffs and the Class to bear unnecessary expenses for the defective devices, replacement costs, and other medical expenses associated with such, allowing Defendant to be unjustly enriched at the expense of Plaintiffs and the Class.

40. Furthermore, Defendant's concealment of the defect and failure to disclose said defect to physicians and Class members allowed the Recalled Cardiac Devices to be marketed and sold as safe for their prescribed use, when in fact they were not. This conduct amounts to a deliberate act, which Defendant had reason to know was wanton, reckless and dangerous to patients and Plaintiffs' and Class members participants.

41. On October 26, 2005, the *Wall Street Journal* reported that the medical device firms of St. Jude, of St. Paul, Minn., Guidant, of Indianapolis, and Medtronic were served with subpoenas from the U.S. Attorney's Office in Boston, Massachusetts. The article further stated that the subpoena dealt "with defibrillators, pacemakers, 'lead' wires and related products."

42. The October 26th article reported that the subpoena served on Medtronic in particular was "inquiring into 'provision of benefit, if any, to anyone in a position to recommend

purchases of defibrillators, pacemakers and related devices. The Minneapolis company said authorities also inquired about company training materials for its salespeople relating to federal anti-kickback laws.”

E. The Effect of Medtronic’s Wrongful Conduct

43. Medtronic widely and successfully marketed the Recalled Cardiac Devices in the United States and the State of Minnesota. This included aggressive marketing and promotional campaigns extolling the qualities and virtues of the Recalled Cardiac Devices as reliable and mechanically sound for mitigating the risk of heart failure.

44. As a direct and proximate cause of Defendant’s conduct and the Recalled Cardiac Devices, Plaintiffs’ participants have suffered injuries and/or received related medical treatment and care. Accordingly, Plaintiffs have incurred and will likely incur full or partial costs for the Recalled Cardiac Devices and related medical costs including, but not limited to, the original defective device, implantation surgery, replacement surgery, medical monitoring and/or other related healthcare costs.

45. Defendant, despite its offer to replace the device, made no offer to reimburse the cost of the original defective device or to absorb the associated medical costs resulting from the replacement. Defendant offered merely to provide a replacement device and provide a small amount of money for *unreimbursed medical expenses to patients, not to Class members*.

46. Defendant’s offer to replace the Recalled Cardiac Devices (under limited conditions) with devices from its inventory is also unsatisfactory to most patients, doctors, and Class members given the expected loss of confidence in Medtronic and the failure of its ICDs and CRT-Ds.

V. CLASS ALLEGATIONS

47. Plaintiffs bring this action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(2) and (3) on behalf of themselves and all others similarly situated. The members of the class consist of:

All third party payors in the United States and its Territories who (i) have been a party to a contract, issuer of a policy or sponsor of a plan which contract, policy or plan provides medical coverage to natural persons, and (ii) have incurred, pursuant to such contract, policy or plan, full or partial costs (other than as premiums) for Recalled Cardiac Devices and related medical costs including implantation surgery, replacement surgery, medical monitoring and/or other hospital costs (the "Class"). The Class shall exclude governmental entities, Defendant, including its officers, directors, subsidiaries and affiliates, Plaintiffs' counsel and the Judge of the Court to which this case is assigned.

48. The Class is so numerous that individual joinder of all its members is impracticable.

49. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Even if every Class member could afford individual litigation, the court system could not as it would be unduly burdensome to the courts in which the individual litigation of thousands of cases would proceed. Individual litigation presents a potential for inconsistent or contradictory judgments, the prospect of a race to the courthouse, and an inequitable allocation of recovery among those with equally meritorious claims. Individual litigation also increases the expense and delay to all parties and the court system in resolving the legal and factual issues common to all claims regarding the Recalled Cardiac Devices. By contrast, the class action device presents far fewer management difficulties while providing the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

50. Each Plaintiff's claims are typical of the claims of the Class. Plaintiffs and all members of the Class have the same damages and are facing further damages arising out of Defendant's common course of conduct as alleged herein. The economic losses of each Class member were and are caused directly by Defendant's conduct as alleged herein. Plaintiff and other members of the Class must prove the same facts in order to establish the same claims, described herein, which apply to all Class members.

51. There are questions of law and fact common to the Class, including but not limited to:

- a. Whether Defendant negligently and/or fraudulently distributed, promoted, tested, sold and/or marketed the Recalled Cardiac Devices;
- b. Whether there are design and/or manufacturing defects in the Recalled Cardiac Devices that cause an increased risk of battery failure and/or short-circuit creating a risk of injury and death;
- c. Whether the increased risk of battery failure and/or short-circuit requires additional medical procedures, periodic diagnostic studies, medical examinations and/or medical research;
- d. How frequently the already-implanted Recalled Cardiac Devices should be monitored by physicians to determine the risk of short-circuit;
- e. Whether the increased risk of battery failure and/or short-circuit render the Recalled Cardiac Devices unsafe, unsuitable and/or unreasonably dangerous for human use;
- f. Whether Defendant's conduct in designing, manufacturing, marketing, and monitoring the Recalled Cardiac Devices and their batteries fell below the duty of care owed by Defendant to the Class;
- g. Whether Defendant conducted adequate study, testing and analysis to determine if, and to what extent the Recalled Cardiac Devices, used in accordance with Defendant's instructions, were defective and unsafe;
- h. Whether Defendant failed to comply with FDA standards and requirements in the design, manufacture and approval of the Recalled Cardiac Devices;

- i. Whether Defendant engaged in unconscionable, deceptive and/or unreasonable business practices and conduct;
- j. Whether Defendant knowingly, intentionally, recklessly or negligently concealed, suppressed or omitted material information concerning the safety of Recalled Cardiac Devices from physicians, hospitals, implant recipients and the Class;
- k. Whether Defendant's conduct constitutes constructive fraud;
- l. Whether the Defendant falsely and fraudulently misrepresented in its advertisements, promotional materials and other materials, the safety, quality and usefulness of the Recalled Cardiac Devices;
- m. Whether the Class has been injured by virtue of the Defendant's deceptive business practices and conduct;
- n. Whether the Class is entitled to injunctive and other equitable relief including restitution and disgorgement and, if so, the nature of such relief;
- o. Whether the Class is entitled to medical monitoring and treatment, at Defendant's expense;
- p. Whether the Class is entitled to compensatory damages and, if so, the nature and amount of such damages; and
- q. Whether Defendant is liable for punitive or exemplary damages and, if so, the amount necessary and appropriate to punish it for its conduct, deter others and fulfill all other policies and purposes of punitive and exemplary damages.

52. These and other questions of law and/or fact are common to the Class and predominate over any questions affecting only individual Class members.

53. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Class. Plaintiffs have retained counsel competent and experienced in the prosecution of complex class action, consumer fraud, products liability and mass tort litigation. Plaintiffs have no claims antagonistic to those of the Class. Plaintiffs' counsel will fairly and adequately protect the interests of the Class.

VI. CLAIMS FOR RELIEF

COUNT I

VIOLATION OF MINNESOTA FALSE STATEMENTS IN ADVERTISING STATUTE

54. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

55. Defendant produced and published advertisements and deceptive and misleading statements of the soundness and mechanical reliability of the Recalled Cardiac Devices after learning of their inherent defects with the intent to sell the Recalled Cardiac Devices.

56. Defendant concealed its deceptive practices in order to increase the sale of and profit from the Recalled Cardiac Devices.

57. Defendant engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the Minnesota False Statements in Advertising Statute, Minn. Stat. § 325F.67 *et seq.*, when it failed to comply with FDA requirements and when it failed to adequately warn consumers and the medical community of the safety risks associated with the Recalled Cardiac Devices. As a direct result of Defendant's deceptive, unfair, unconscionable, and fraudulent conduct and violation of Minn. Stat. § 325F.67 *et seq.*, Plaintiffs and the Class were injured in that they paid substantial sums for the Recalled Cardiac Devices and for the costs of replacing the Recalled Cardiac Devices that they would not have paid had Defendant not engaged in unfair and deceptive conduct.

58. Defendant systematically and continually conducts business throughout the state of Minnesota in that (1) it maintains offices in Minnesota and its CRM division is headquartered in the state; (2) Defendant's CRM facilities operate in Minneapolis, Minnesota, which is its principal place of business for manufacturing, research and development, administration,

marketing and sales, warehousing, packaging, and shipping of the Medtronic Devices; and (3) it markets, advertises, and sells the Medtronic Devices within Minnesota.

59. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs and other third party payors have incurred health care costs related to the Recalled Cardiac Devices that have been paid by them but are the responsibility of Defendant, in an amount to be determined at trial.

COUNT II
VIOLATION OF THE MINNESOTA DECEPTIVE TRADE PRACTICE ACT

60. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

61. Defendant applied advertising and marketing campaigns representing the Recalled Cardiac Devices as mechanically sound and medically safe, while Medtronic knew of the defects in the devices. Defendant continued these campaigns of deception until 2005, when the tragic death of a young man and the FDA demands for a public recall disclosed the company's deceptive practices.

62. Defendant knew or should have known of the defective nature of the Recalled Cardiac Devices but denied public access to the information, to avoid corporate responsibility. Defendant knew its patients and their physicians were at a disadvantage in accessing information involving the safety of its affected devices.

63. Defendant concealed the design defects of its device for the purposes of higher profits and increased sales.

64. Defendant has violated Minn. Stat. §325D.44. The violations include the following.

65. Defendant has violated Minn. Stat. §325D.44 (5) by representing the Recalled

Cardiac Devices as having characteristics, uses, and benefits of a safe and mechanically sound device while knowing the statements were false and the devices contained inherent design defects.

66. Defendant has violated Minn. Stat. § 325D.44 (7) by representing the Recalled Cardiac Devices as a non-defective medical product of a particular standard, quality, or grade while knowing the statements were false and the devices contained inherent design defects.

67. Defendant has violated Minn. Stat. § 325D.44 (9) by advertising, marketing, and selling the Recalled Cardiac Devices as medically reliable and without a known design defect while knowing those claims were false and without any medical support.

68. Defendant has violated Minn. Stat. § 325D.44 (13) by creating a likelihood of confusion about the efficacy and mechanical soundness of its medical device, comparing the Recalled Cardiac Devices with other non-defective products.

69. The Minnesota statutes prohibiting unfair and deceptive trade practices apply because Defendant's deceptive scheme was carried out in Minnesota and affected Plaintiffs and other third party payers whose beneficiaries were implanted with the Recalled Cardiac Devices containing the known defects.

70. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs and other third party payers have incurred health care costs related to the Recalled Cardiac Devices that have been paid by them, but are the responsibility of Defendant, in an amount to be proven at trial.

COUNT III
VIOLATION OF THE MINNESOTA PREVENTION OF CONSUMER FRAUD ACT

71. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

72. Defendant intentionally concealed its design defect and failed to disclose for the purposes of continuing the sale and distribution of the Recalled Cardiac Devices.

73. Defendant represented that the Recalled Cardiac Devices were safe and effective and intended that patients and physicians rely on those representations when deciding if Defendant's device was optimal for meeting the patient's needs.

74. Through these misleading and deceptive statements and false promises, Defendant violated Minn. Stat. § 325F.69.

75. The Minnesota statutes prohibiting consumer fraud apply to all of Defendant's transactions with Plaintiffs and other third party payer beneficiaries implanted with the Recalled Cardiac Devices because Defendant's deceptive scheme was carried out in Minnesota and affected Plaintiffs and other third party payers.

76. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs and other third party payers have incurred health care costs related to the Recalled Cardiac Devices which have been paid by them, but are the responsibility of Defendant, in an amount to be proven at trial.

**COUNT IV
UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW**

77. Plaintiffs hereby incorporate by reference the preceding paragraphs as if fully set forth herein.

78. Defendant had a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of the Recalled Cardiac Devices.

79. Had the Defendant not engaged in the deceptive conduct described above, Plaintiffs and members of the Class would not have purchased and/or paid for the Recalled Cardiac Devices, and would not have incurred related medical costs.

80. Defendant's deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs and Class members, constituted unfair and deceptive acts and practices in violation of the state consumer protection statutes listed below.

81. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff and Class members for the Recalled Cardiac Devices and for the costs of replacing the Recalled Cardiac Devices that they would not have paid had Defendant not engaged in unfair and deceptive conduct.

82. Defendant's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of state consumer protection statutes, as listed below:

a. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

b. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et. seq.*;

c. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et. seq.*;

d. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et. seq.*;

e. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code §1770, *et seq.* and Cal. Bus. & Prof. Code § 17200, *et. seq.*;

f. Defendant has engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et. seq.*;

g. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110a, *et. seq.*;

h. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code §§ 2511, *et. seq.* and 2531, *et seq.*;

i. Defendant has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et. seq.*;

j. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et. seq.*;

k. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §§10-1-372, *et. seq.*, 10-1-392 and 10-1-420.

l. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480-1, *et. seq.*;

m. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et. seq.*;

n. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et. seq.*;

o. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5-1, *et. seq.*;

p. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.16, *et. seq.*;

q. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et. seq.*;

r. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.170, *et. seq.*;

s. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et. seq.*;

t. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 205A, *et. seq.*;

u. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et. seq.*;

v. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et. seq.*;

w. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Comp. Laws Ann.. § 445.901, *et. seq.*;

x. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §§ 325D.43, *et seq.*; 325F.67, *et seq.*; and 325F.68 *et seq.*;

y. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et. seq.*;

z. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Ann. Missouri Stat. § 407.010, *et. seq.*;

aa. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Ann. § 30-14-101, *et. seq.*;

bb. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et. seq.*;

cc. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. Ann. § 598.0903, *et. seq.*;

dd. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et. seq.*;

ee. Defendant has engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, *et. seq.*;

ff. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et. seq.*;

gg. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§ 349 *et. seq.* and 350-e, *et seq.*;

hh. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et. seq.*;

ii. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. CODE §§ 51-12-01, *et. seq.*, and 51-15-01, *et seq.*;

jj. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et. seq.*;

kk. Defendant has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, *et. seq.*;

ll. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et. seq.*;

mm. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et. seq.*;

nn. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et. seq.*;

oo. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et. seq.*;

pp. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws § 37-24-1, *et. seq.*;

qq. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et. seq.*;

rr. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et. seq.*;

ss. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code. § 13-11-1, *et. seq.*;

tt. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, *et. seq.*;

uu. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et. seq.*;

vv. Defendant has engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, *et. seq.*;

ww. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et. seq.*;

xx. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. §100.20, *et. seq.*; and

yy. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-101, *et. seq.*

83. Plaintiffs and the Class were injured by the cumulative and indivisible nature of Defendant's conduct. The cumulative effect of Defendant's conduct directed at patients, physicians and consumers was to create demand for and sell the Recalled Cardiac Devices. Each aspect of Defendant's conduct combined to artificially create sales of the Recalled Cardiac Devices.

84. The medical community relied upon Defendant's misrepresentations and omissions in determining which cardiac device to utilize.

85. By reason of the unlawful acts engaged in by Defendant, Plaintiffs and other third party payors have suffered ascertainable loss and damages.

86. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs and other third party payors were damaged by paying for these devices.

87. As a direct and proximate result of Medtronic's conduct, Plaintiffs and the Class have incurred and will likely incur full or partial costs for Recalled Cardiac Devices and related medical costs including implantation surgery, replacement cardiac devices, replacement surgery, medical monitoring and/or other hospital costs, in an amount to be proven at trial.

88. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs and the Class are entitled to compensatory damages, treble damages, attorneys' fees, and costs of suit.

COUNT V
SUBROGATION LIABILITY DETERMINATION

89. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

90. Throughout the relevant period, Plaintiffs and the Class provided a full spectrum of health benefit products, including, but not limited to, managed care products, third party administration services, and indemnity products to groups and individuals on both an insured and an employer funded basis. Each of these products was provided to members injured by the Recalled Cardiac Devices.

91. The damages sustained by Plaintiff and the Class include but are not limited to damages for all benefits paid for or provided to plan members or insureds, said damages being incurred as a result of the plan members or insureds being injured by or seeking treatment as a proximate result of utilization of the Recalled Cardiac Devices.

92. Plaintiffs and the Class provided these and other benefits to their insureds and plan members not as volunteers but pursuant to their obligations under contractual agreements specifying the respective rights and obligations of the Plaintiffs and the Class and their members or insureds. These agreements specifically grant Plaintiffs and the Class broad subrogation and reimbursement rights.

93. Plaintiffs and the Class provided benefits to their plan members and insureds and possess subrogation and reimbursement rights per either contractual provisions granting each of them such or equitable subrogation under the substantive law of the jurisdictions in which they are located and in which Defendant sold its products.

94. Plaintiffs and the Class have contractual and equitable rights of subrogation and reimbursement against Defendant to recover damages to the extent of health benefits paid or

provided on behalf of members, employees and insureds implanted with the Recalled Cardiac Devices.

95. As a result of their subrogation and reimbursement rights, Plaintiffs and the Class hereby seek injunctive relief in the form of creation of a class under Fed. R. Civ. P. 23(b)(2) or other applicable law for a classwide determination of Defendant's liability as well as disclosure by Defendant of records sufficient (and solely) for purposes of identifying insureds, employees or members for whom Plaintiffs and the Class have subrogation or reimbursement claims.

COUNT VI UNJUST ENRICHMENT

96. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

97. To the detriment of Plaintiffs and Class members, Defendant has been, and continues to be unjustly enriched as a result of the unlawful and/or wrongful collections of, *inter alia*, payments for the Recalled Cardiac Devices and associated costs.

98. In exchange for the payments made for the Recalled Cardiac Devices, and at the time they made these payments, Plaintiffs and the Class expected that the Recalled Cardiac Devices were safe and medically effective treatment for the condition, disorder, or symptom for which they were prescribed.

99. The cumulative effect of Defendant's conduct directed at physicians and consumers was to artificially create demand for Recalled Cardiac Devices. Plaintiffs and the Class were injured by the cumulative and indivisible nature of Medtronic's conduct.

100. As an intended and expected result of its conscious wrongdoing as set forth in this Complaint, Defendant has profited and benefited from payments Plaintiffs and the Class made

for the Recalled Cardiac Devices and from payments Plaintiffs and the Class have made for replacements for the Recalled Cardiac Devices.

101. In exchange for the payments they made for the Recalled Cardiac Devices, and at the time they made these payments, Plaintiffs and the Class expected that the Recalled Cardiac Devices were safe and medically effective treatment for the condition, illness, disorder, or symptom for which they were prescribed.

102. Defendant has voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of its wrongdoing, Plaintiffs and the Class paid for the Recalled Cardiac Devices and were forced to pay for replacement devices when they otherwise would not have done so. The failure of Defendant to provide Plaintiffs and the Class with the remuneration they expected enriched Defendant unjustly.

103. Plaintiffs and the Class are entitled in equity to seek restitution of Defendant's wrongful profits, revenues, and benefits to the extent and in the amount deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendant's unjust enrichment.

104. Accordingly, Plaintiffs and the Class seek full restitution of Defendant's enrichment, profits, revenues, benefits and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

COUNT VII NEGLIGENCE

105. Plaintiffs hereby incorporate by reference the preceding paragraphs as if fully set forth herein.

106. Defendant had a duty to Plaintiffs and the Class to comply with FDA standards and regulations, use reasonable care in the design, manufacture, and testing of its devices,

provide a safe product in design and manufacture, and warn Plaintiffs and the Class of the defective nature of the Recalled Cardiac Devices at the earliest possible date. Defendant breached its duty of reasonable care to Plaintiffs and the Class by incorporating a defect into the design of said devices, thereby causing economic injuries to Plaintiffs and members of the Class.

107. Defendant breached its duty of reasonable care to Plaintiffs and the Class by manufacturing and assembling the Recalled Cardiac Devices in such a manner that they were prone to fail to operate and malfunction and expose Plaintiffs and members of the Class to economic injuries.

108. Defendant breached its duty of reasonable care to Plaintiffs and the Class by failing to notify Plaintiffs and the Class at the earliest possible date of known design defects in the Recalled Cardiac Devices.

109. Defendant breached its duty of reasonable care to Plaintiffs and the Class by failing to comply with the FDA's Pre-Market Approval standards for the devices.

110. Defendant breached its duty of reasonable care to Plaintiffs and the Class by failing to exercise due care under the circumstances.

111. As a direct and proximate result of the carelessness and negligence of Defendant, as set forth in the preceding paragraphs, Plaintiffs and members of the Class have sustained and will continue to sustain economic losses and other damages, and are therefore entitled to compensatory damages and equitable and declaratory relief according to proof.

**COUNT VIII
NEGLIGENCE PER SE**

112. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

113. Defendant had an obligation not to violate the law in the manufacture, design, testing, manufacturing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Recalled Cardiac Devices, and otherwise distributing the Recalled Cardiac Devices.

114. Defendant's acts constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendant to civil liability for all damages arising there from, under theories of negligence per se.

115. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs and other third party payers have suffered damages including incurring health care costs that have been paid by them, but are the responsibility of Defendant, in an amount to be proven at trial.

**COUNT IX
STRICT LIABILITY – FAILURE TO WARN**

116. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

117. At all relevant times hereto, Defendant was engaged in the development, testing, manufacturing, marketing and sales of implantable cardiac defibrillators ("ICDs") and cardiac resynchronization therapy devices ("CRT-Ds"), including the batteries required for their operation. Defendant designed, manufactured, assembled and sold these devices to medical professionals, knowing that they would then be implanted in patients with heart disease and disorders. Defendant knew the costs of the devices and related medical expenses would then be passed on in whole or in part to Plaintiffs' participants and thereby Plaintiffs and all other members of the Class.

118. Defendant distributed and sold the Recalled Cardiac Devices in the condition in which they left their place of manufacture, in their original form of manufacture, which included the defects described herein. The Recalled Cardiac Devices were expected to and did reach Plaintiffs' participants without substantial change in their condition as manufactured and sold by Defendant. At no time did Plaintiffs or the other Class Members have reason to believe that the devices were in a condition not suitable for their proper and intended use among the patients in whom they were to be implanted.

119. The Recalled Cardiac Devices designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendant were in a dangerous and defective condition and posed a threat to any user or consumer of the devices. Plaintiffs and Class members were and are in a class of persons that Defendant should have considered to be subject to the harm caused by the defective nature of the devices.

120. The devices were implanted and used in the manner for which they were intended, that is for the detection, correction, and prevention of serious and/or life-threatening harm through surgical implantation. This use has resulted in injury to Plaintiffs and all other members of the Class.

121. Plaintiffs and members of the Class were not able to discover, nor could they have discovered through the exercise of reasonable care, the defective nature of the Recalled Cardiac Devices. Further, in no way could Plaintiffs or the other members of the Class have known that Defendant had designed, developed, and manufactured the devices in such a way as to increase the risk of harm, injury or death to the recipients of the devices.

122. As a direct and proximate cause of the design, development, manufacture, marketing, and sales of the Recalled Cardiac Devices, Plaintiffs and all other Class members

have sustained and will continue to sustain economic losses, and are, therefore, entitled to compensatory relief in an amount to be proven at trial. Further, Plaintiffs and Class members are entitled to a declaratory judgment that Defendant is liable for breach of their duty to Plaintiffs and Class members and failure to provide a safe and effective medical device. Plaintiffs and the Class are also entitled to equitable relief.

COUNT X
STRICT LIABILITY – DESIGN AND MANUFACTURING DEFECT

123. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

124. The Recalled Cardiac Devices are defectively designed and manufactured because the foreseeable risks of mechanical malfunction and failure outweigh the benefits associated with the devices.

125. The Recalled Cardiac Devices were expected to and did reach the beneficiaries of Plaintiffs and other third party payers without substantial change or adjustment to their mechanical function upon implanting the device.

126. Defendant knew or should have known of the design and manufacturing defect and the risk of serious bodily injury that exceeded the benefits associated with the design of the Recalled Cardiac Devices.

127. Furthermore, the Recalled Cardiac Devices and their defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

128. The Recalled Cardiac Devices were defective due to inadequate warnings or instruction because Defendant knew or should have known that the devices created a high risk of bodily injury and serious harm. Defendant failed to adequately and timely warn consumers of this risk.

129. The Recalled Cardiac Devices are inherently dangerous for their intended use due to design and manufacturing defect and improper functioning. Defendant is therefore strictly liable.

130. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs and other third party payers have incurred health care costs related to the Recalled Cardiac Devices which have been paid by them, but are the responsibility of Defendant, in an amount to be proven at trial.

COUNT XI
BREACH OF EXPRESS WARRANTY

131. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

132. Defendant expressly warranted to Plaintiffs and other third party payers by and through Defendant or its authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, medical patients, and the general public, that the Recalled Cardiac Devices were safe, effective, fit and proper for its intended use.

133. In allowing the implantation of the Recalled Cardiac Devices beneficiaries of Plaintiffs and other third party payers relied on the skill, judgment, representations, and express warranties of Defendant. These warranties and representations were false in that the Recalled Cardiac Devices were not safe and were unfit for the uses for which they were intended.

134. Through its sale of the Recalled Cardiac Devices, Defendant was a merchant pursuant to Section 2-314 of the Uniform Commercial Code.

135. As a direct and proximate result of Defendant's breaches of warranties, Plaintiffs and other third party payers have incurred health care costs related to the Recalled Cardiac

Devices that have been paid by them, but are the responsibility of Defendant, in an amount to be proven at trial.

**COUNT XII
BREACH OF IMPLIED WARRANTY**

136. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

137. Prior to the time that beneficiaries of Plaintiffs and other third party payers were implanted with the Recalled Cardiac Devices, Defendant impliedly warranted to them that the Recalled Cardiac Devices were of merchantable quality and safe and fit for the use for which they were intended.

138. Plaintiffs and other third party payers were and are unskilled in the research, design and manufacture of the Recalled Cardiac Devices, and reasonably relied entirely on the skill, judgment, and implied warranty of Defendant in allowing the implantation of the Recalled Cardiac Devices.

139. Defendant breached the implied warranty for the Recalled Cardiac Devices because said devices were defective, unmerchantable, and not fit for their intended purpose.

140. As a direct and proximate result of Defendant's breaches of warranties, Plaintiffs and other third party payers have incurred health care costs related to the Recalled Cardiac Devices that have been paid by them, but are the responsibility of Defendant, in an amount to be proven at trial.

**COUNT XIII
BREACH OF ASSUMED CONTRACTUAL WARRANTY OBLIGATIONS**

141. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

142. Defendant has acknowledged its obligation as first party insurer by providing express and implied warranties directly to consumers of its products, and specifically the recalled devices.

143. Defendant has an obligation to repay Plaintiffs and the Class for all costs incurred with the Recalled Cardiac Devices because it has acknowledged a responsibility under its warranties to make payment with regard to the recalled devices.

144. As a direct and proximate result of Defendant's breaches of its assumed contractual duties, Plaintiffs and other third party payers have incurred health care costs related to the Recalled Cardiac Devices that have been paid by them, but are the responsibility of Defendant, in an amount to be proven at trial.

**COUNT XIV
MISREPRESENTATION BY OMISSION**

145. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

146. Defendant misrepresented the mechanical soundness and reliability of the Recalled Cardiac Devices through promotional and marketing campaigns. Defendant continued this misrepresentation for an extended period of time, without disclosing material information.

147. Defendant took advantage of the limited opportunity beneficiaries of Plaintiffs and other third party payers (and their physicians) had to discover Defendant's intentional concealment of the defects and risks in the Recalled Cardiac Devices.

148. Defendant concealed these design defects by withholding information pertaining to the inherent design defects and high risks of failure relating to the Recalled Cardiac Devices, and presenting the devices as safe and reliable.

149. Defendant's intentional misrepresentations and omissions were made willfully, wantonly or recklessly to the beneficiaries of Plaintiffs and third party payers (through their physicians) to induce purchase of the Recalled Cardiac Devices over its competitors.

150. Defendant knew or should have known of the high risk beneficiaries of Plaintiffs and other third party payers would encounter by unwittingly agreeing to have implanted the Recalled Cardiac Devices.

151. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs and other third party payers have incurred health care costs related to the Recalled Cardiac Devices that have been paid by them, but are the responsibility of Defendant, in an amount to be proven at trial.

VII. DEMAND FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, request that this Court enter the following relief:

- a. Under Fed. R. Civ. P 23(g)(2)(A), this Court designate interim counsel to act on behalf of the putative class before determining whether to certify the action as a class action;
- b. Under Fed. R. Civ. P 23(b)(2) and (3), this Court enter an Order certifying that the actions may be maintained as class actions;
- c. Under all counts, the Court enter a preliminary injunction in joining the Defendant, Medtronic Inc., from failing to provide to class counsel, under appropriate Court-ordered terms under HIPAA, the registrant list(s) before the Recalled Cardiac Devices;
- d. Under all counts, an award of appropriate monetary and non-monetary relief including the court enter judgment available compensatory damages, statutory damages, punitive damages, reasonable attorneys fees and expenses;
- e. On the Subrogation Liability Determination count for Plaintiffs and the Class, equitable and injunctive relief in the form of creation of a Fed. R. Civ. P. 23(b)(2) class for determining Defendant's liability to Plaintiff and the Class and a HIPAA-compliant Order for Defendant to provide to Plaintiff and the Class its register of patients implanted with the defective Recalled Cardiac Devices;

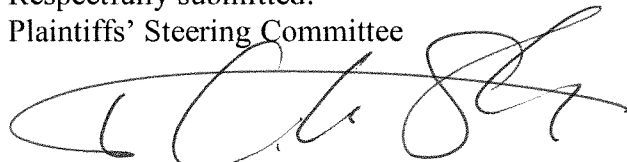
- f. For medical monitoring, whether denominated as damages or in the form of equitable relief;
- g. For Plaintiffs' costs and expenses of this litigation, including all reasonable attorneys' fees and expert fees; and
- h. Plaintiffs and the Class be granted such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable and proper by this Court.

VIII. DEMAND FOR JURY TRIAL

Plaintiffs and the Class hereby demand a trial by jury as to all claims in this action.

Date: February 15, 2006

Respectfully submitted:
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